K140534

MAR 2 7 2014

# 510(k) Summary

| | |
|---|---|
| **Introduction** | According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence. |
| **Submitter Name, Address, Contact** | Roche Diagnostics<br>9115 Hague Road, P.O. Box 50416<br>Indianapolis, IN 46250-0416<br><br>Contact Person: Jane Phillips<br>Phone: 317-521-3338<br>Fax: 317-521-2324<br>Email: jane.phillips@roche.com<br><br>Date Prepared: March 12, 2014 |

**Device Name**

Proprietary name: Elecsys PreciControl TS

Common name: Elecsys PreciControl TS

Classification name: Quality control material (assayed and unassayed)

**Establishment Registration**

For the Elecsys PreciControl TS, the establishment registration number (Roche Diagnostics GmbH Mannheim) is 9610126. The establishment registration number for Roche Diagnostics United States is 1823260.

**Classification**

The FDA has classified the product as a Class I Reserved device.

| Panel | Product Code | Classification Name | Regulation Citation |
|---|---|---|---|
| Clinical Chemistry | JJX | Quality control material (assayed and unassayed) | 862.1660 |

**Predicate Device**

The Elecsys PreciControl TS is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys PreciControl TSH (k962573).

**Device Description**

The Elecsys PreciControl TS is a lyophilized product consisting of human TSH at a euthyroid level in an equine serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels. All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

**Intended Use**

Elecsys PreciControl TS is used for quality control of the Elecsys TSH immunoassay on the Elecsys and cobas e immunoassay analyzers.

**Substantial Equivalence**

The Elecsys PreciControl TS is equivalent to the Elecsys PreciControl TSH (k962573).

*Continued on next page*

**Comparison Table**

Table 1 below compares Elecsys PreciControl TS with the predicate device, PreciControl TSH.

**Table 1. Comparison of Candidate and Predicate Device**

| Characteristic | Elecsys PreciControl TS (Candidate Device) | Elecsys® PreciControl TSH (k962573) |
|---|---|---|
| **Intended Use** | Elecsys PreciControl TS is used for quality control of the Elecsys TSH immunoassay on the Elecsys and **cobas e** immunoassay analyzers. | PreciControl TSH is used for quality control of the Elecsys TSH immunoassay on the Elecsys and **cobas e** immunoassay analyzers. |
| **Format** | Lyophilized material needs to be reconstituted with 2.0 mL of distilled or deionized water. | Liquid (2.0 mL) |
| **Analyte** | Recombinant human TSH | Same |
| **Matrix** | Equine serum | Same |
| **Levels** | One | Same |
| **Target Ranges** | TSH: ~0.2 µIU/mL | Same |
| **Stability** | Lyophilized:<br>• Up until labeled expiration date at 2-8°C<br><br>Reconstituted:<br>• -20°C: 31 days (1 month) (freeze only once)<br>• 2-8° C: 72 hours (3 days)<br>• on the analyzers (20-25°C): up to 5 hours | Unopened:<br>• Store at 2-8°C until expiration date<br><br>Opened:<br>• Unopened at 2-8°C: Up to the stated expiration date<br>• Opened at 2-8°C: 12 weeks<br>• on the analyzers (20-25°C): up to 5 hours |

*Continued on next page*

**Table 1. Comparison of Candidate and Predicate Devices,** continued

| Characteristic | Elecsys PreciControl TS (Candidate Device) | Elecsys® PreciControl TSH (k962573) |
|---|---|---|
| **Handling** | Carefully dissolve the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding foam formation.<br><br>Transfer aliquots (500µl) of the reconstituted control into empty labeled snap-cap bottles (ControlSet Vials)<br><br>Attach the supplied labels to the additional bottles. Store the aliquots immediately at -20°C.<br><br>Discard of aliquot after performing the control procedure since they should be used only once. | The control is supplied ready-for-use in bottle compatible with the system. The control should only be left on the analyzer during performance of quality control. After use, close the bottle as soon as possible and store at 2-8°C. Because of possible evaporation effects, not more than 20 quality control procedures per bottle should be performed. |
| **Traceability** | The Elecsys TSH assay was standardized against the 2nd IRP WHO Reference Standard 80/558 | Same |

**Performance Characteristics**

The Elecsys PreciControl TS was evaluated for value assignment, stability, and reconstitution.

**Conclusion**

The data demonstrate that the performance of the Elecsys PreciControl TS is substantially equivalent to that of the predicate device, Elecsys® PreciControl TSH.

## Value Assignment

**Procedure for Value Assignment**

1. **Standardization and traceability**
   The PreciControl TS is assigned an analyte-specific value with the Elecsys TSH immunoassay. The Elecsys TSH assay was standardized against the 2nd IRP WHO Reference Standard 80/558.

2. **Value Assignment**
   Values are assigned for each lot of PreciControl TS in combination with each assay reagent lot available. The controls are run in duplicate on at least three (3) MODULAR ANALYTICS E170 measuring cells. The assigned value of each control level is defined as the median value obtained over at least six (6) determinations of the respective control level.

   Acceptance Criteria for Value assignment, specified in Table 2.

   **a.** Precision of the control determinations
   **b.** Percent difference between assigned and target (nominal) values
   **c.** Analyzer-to-analyzer variability

   For additional analyzer platforms, the same value assignment procedure is performed. The assigned values obtained on the additional analyzers are compared to those obtained on the MODULAR ANALYTICS E170 (the master analyzer).

**Table 2. Value Assignment Acceptance Criteria for PreciControl TS**

| | Target Value [µIU/mL] | (a) Precision, % CV | (b) Acceptance range of Assigned Value, [%] | (c) Assigned value on Additional vs. Master Platform, % |
|---|---|---|---|---|
| **TSH** | 0.2 | 9 | 60-140 | 90-110 |

**Conclusion:** Acceptance criteria for all stages of the process were met, supporting the target values and ranges above.

## Stability Studies

**Stability Studies**

Three studies were performed in order to verify the stability claims for the PreciControl TS.

All stability studies were performed on the cobas e 411 analyzer.

**Study 1 and 2. Stability after Reconstitution:**

**Study 1**
The on-test and reference materials were tested in duplicate. The on-test material was reconstituted and stored for 73 h at +2°C to +8°C and afterwards stored in snap-cap bottles for 6h at +20°C to 25°C. The reference material was lyophilized material stored at +2°C to +8°C. The on-test recovery was calculated as a percent of the reference value.

The PreciControl TS lot was evaluated in duplicate on the cobas e 411. The acceptance criterion was 90-110% recovery of the reference material value.

**Table 3. Stability of Reconstituted Lyophilized PreciControl TS**

| Stability of reconstituted PreciControl TS on cobas e 411 | | | |
|---|---|---|---|
| **Sample** | **Reference [µIU/mL]** | **Stressed control [µIU/mL]** | **% Recovery** |
| PC TS | 0.174 | 0.168 | 96.6 |

*Continued on next page*

## Stability Studies

**Stability Studies**

**Study 2**
The on-test and reference materials were tested in duplicate. The on-test material was reconstituted and stored for 32 days at -20°C and afterwards stored in snap-cap bottles for 6h at +20°C to 25°C. The reference material was lyophilized material stored at +2°C to +8°C. The on-test recovery was calculated as a percent of the reference value.

The PreciControl TS lot was evaluated in duplicate on the cobas e 411. The acceptance criterion was 90-110% recovery of the reference material value.

**Table 4. Stability of Reconstituted Lyophilized PreciControl TS**

| Stability of reconstituted Lyophilized on cobas e 411 | | | |
|---|---|---|---|
| **Sample** | **Reference [µIU/mL]** | **Stressed control [µIU/mL]** | **% Recovery** |
| PC TS | 0.174 | 0.177 | 101.7 |

**Conclusion:** The data support the package insert claim that reconstituted PreciControl TS is stable for up to:

31 days at -20°C
72 hours at 2-8°C
5 h at 20-25°C on the analyzers

*Continued on next page*

## Stability Studies

**Stability Studies continued**

**Study 3. Real-Time Stability:**

The real-time stability is being evaluated as follows:

In the on-going real-time stability study, the PreciControl TS test material is stored at +2 to +8°C. The controls are tested at specified intervals over the shelf life of the device up to the planned shelf life plus one month.

Data for the time-points at 6, 12, 16, 19, 25 and 37 months tested in duplicate will be available. The average on-test recovery value is calculated as percent recovery compared to the unstressed reference value (stored at -20°C).

The acceptance criterion is a recovery of 90-110% of the unstressed reference.

Currently, the shelf life claim is 24 months. This is based on real-time stability data of three lots.

The testing will be continued with this stability protocol until data is available to support a claim of 36 months.

**Conclusion:** Data support the current package insert claim of shelf life of 24 months.

**Table 5. Real-time Stability testing plan for PreciControl TS**

| Lot | Level | On-Test as a Percent of Reference, % | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Month | | | | | | |
| | | 6 | 9 | 12 | 16 | 19 | 25 | 37 |
| DR01 | TSH | 106 | 100 | 103 | 99 | 103 | 102 | |
| DR02 | TSH | 99 | 100 | 103 | 98 | 102 | 102 | |
| DR03 | TSH | 100 | 99 | 95 | 99 | 101 | 99 | |

*Continued on next page*

## Reconstitution

**Reconstitution Time Study**

PreciControl TS was reconstituted for 30 minutes (reference) and 60 minutes. Samples were evaluated in duplicate on the cobas e 411 analyzer. The average recovery after 60 minutes of reconstitution will be calculated as percent recovery compared to the value obtained at 30 minutes of reconstitution (the reference value).

The acceptance criterion is recovery of 90-110% of the value obtained for the 30 minute reconstituted material.

**Table 6. Reconstitution Study Results of PreciControl TS**

| Reference result (30 min reconstitution) TS [µIU/mL] | On-Test result (60 min reconstitution) TS [µIU/mL] | % Recovery |
|---|---|---|
| 0.174 | 0.174 | 100.0 |

**Conclusion:** The data support the package insert claim that the PreciControl TS is completely reconstituted after 30 minutes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 27, 2014

ROCHE DIAGNOSTICS
JANE PHILLIPS
REGULATORY PROGRAM MANAGER
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

Re: K140534
Trade/Device Name: Elecsys PreciControl TS
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: February 27, 2014
Received: March 4, 2014

Dear Ms. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
k140534

Device Name
Elecsys PreciControl TS

Indications for Use *(Describe)*
Elecsys PreciControl TS is used for quality control of the Elecsys TSH immunoassay on the Elecsys and cobas e immunoassay analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*